TABLE 4 SUMMARY

1. Date the summary was prepared: March 16, 2012

2. Submitter's name: Guangzhou Wondfo Biotech Co., Ltd.
   Address: South China University of Technology
   Guangzhou, P.R. China 510641
   Phone: 012-86-20-32296069

   Name of contact person: Joe Shia
   LSI International Inc.
   504 East Diamond Ave.,
   Suite F Gaithersburg, MD 20878
   Telephone: 240-505-7880
   Fax: 301-916-6231

3. Name of the device

   Common or usual name: Multi-Drug Urine Test Cup
   Multi-Drug Urine Test Panel

   Trade or proprietary name: Wondfo Multi-Drug Urine Test Cup
   Wondfo Multi-Drug Urine Test Panel

Classification: All are Class II medical devices with the following various product codes with Code of Federal Regulation references:

Product Code	CFR #
DIO	21 CFR 862.3250
LAF	21 CFR 862.3610
DJG	21 CFR 862.3650
DJR	21 CFR 862.3620
LFG	21 CFR 862.3910
LCM	21 CFR 862.3100

4. Description of the device:
   Wondfo Multi-Drug Urine Test Cup and Wondfo Multi-Drug Urine Test Panel are competitive binding, lateral flow immunochromatographic assays for qualitative and simultaneous detection of Cocaine, Methadone, Methamphetamine, Methylenedioxymethamphetamine, Morphine, Morphine 2000, Phencyclidine, Notriptyline in human urine samples.
   A positive urine sample will not generate a colored-line for the specific drug tested in the designated region. A negative urine specimen or a urine sample containing Cocaine, Methadone, Methamphetamine, Methylenedioxymethamphetamine, Morphine, Morphine 2000, Phencyclidine, Notriptyline at the concentration below the designated cutoff levels will generate a colored line in the designated test region for the drug. To serve as a test control, a color line will always appear at the control region.

5. Intended use of the device:
   Wondfo Multi-Drug Urine Test Cup and Wondfo Multi-Drug Urine Test Panel are competitive binding, lateral flow immunochromatographic assays for qualitative and simultaneous detection of Cocaine, Methadone, Methamphetamine, Methylenedioxymethamphetamine, Morphine, Morphine 2000, Phencyclidine, Notriptyline in human urine at the cutoff concentrations of:

Drug(Identifier)	Cut-off level
Cocaine /COC	300 ng/mL
Methamphetamine (MET)	1000 ng/mL
Methylenedioxymethamphetamine (MDMA)	500 ng/mL
Morphine (MOP)	300 ng/mL

Methadone (MTD)	300 ng/mL
Morphine 2000 (OPI)	2000 ng/mL
Phencyclidine (PCP)	25 ng/mL
Notriptyline (TCA)	1000 ng/mL

Configuration of the Wondfo Multi-Drug Urine Test Cup and Wondfo Multi-Drug Urine Test Panel can consist of any combination of the above listed drug analytes.

The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. GC/MS or LC/MS is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.

6. Comparison to the predicate device

Wondfo Multi-Drug Urine Test Cup and Wondfo Multi-Drug Urine Test Panel are a "modified" product format derived from the previously FDA-cleared Wondfo single DOA Tests. The FDA-cleared device and the 510K number are listed in the following Table.

Previously Cleared Wondfo DOA Tests	510K Number	Product Code
Cocaine /COC	K112071	DIO, LAF

Wondfo Multi-Drug Urine Test Cup is a multi-drug test that offers any combination from 2 to 8 drugs of abuse tests while the predicate devices are single-drug test. And the Wondfo Multi-Drug Urine Test Panel is the same as the test dip card format of the predicate devices except that the Wondfo Multi-Drug Urine Test Panel is a multi-drug test that offers any combination from 2 to 8 drugs of abuse tests while the predicate devices are single-drug test.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

10903 New Hampshire Avenue
Silver Spring, MD 20993

Guangzhou Wondfo Biotech Co., LTD.
c/o Joe Shia, LSI International Inc.
504 East Diamond Ave.
Suite F
Gaithersburg, MD 20877

MAY - 8 2012

Re: k121166
Trade Name: Wondfo Multi-Drug Urine Test Cup and Wondfo Multi-Drug Urine Test Panel
Regulation Number: 21 CFR §862.3250
Regulation Name: Cocaine Test System
Regulatory Class: Class II
Product Codes: DIO, LAF, LFG, LCM, DJR and DJG
Dated: March 26, 2012
Received: April 17, 2012

Dear Mr. Shia:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance...

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm

Sincerely yours,

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known):_____

Device Name: Wondfo Multi-Drug Urine Test

Indications for Use:

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Prescription Use __X___ **And/Or** **Over the Counter Use** _X___.
(21 CFR Part 801 Subpart D) **(21 CFR Part 801 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K121166